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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/962,560	10/31/97	HILTON	D 10976

<input type="checkbox"/>	HM22/0110	<input type="checkbox"/> EXAMINER
SCULLY SCOTT MURPHY & PRESSER 400 GARDEN CITY PLAZA GARDEN CITY NY 11530		SRIVASTAVA, D
		<input type="checkbox"/> ART UNIT
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		1653

DATE MAILED: 01/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. <b>08/962,560</b>	Applicant(s) <b>Hilton et al.</b>
Examiner <b>Devesh Srivastava, Ph.D.</b>	Group Art Unit <b>1653</b>

Responsive to communication(s) filed on Aug 29, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 6-12 and 41-51 is/are pending in the application.

Of the above, claim(s) 41-49 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 6-12, 50, and 51 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicants' amendment, filed August 29, 2000, has been entered and fully considered. Claims 6-12 remain pending. Claims 41-51 are newly added. Claims 1-5 and 13-40 have been canceled.

### ***Restriction/Election***

2. Newly submitted claims 41-49 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: SEQ ID NO:3 and NO:4, as identified in the original restriction requirement, are patentably independent and distinct from SEQ ID NO:5-18, 20-48 (see paper No. 12, page 1). Claims 41-49 are drawn to SEQ IDs that are other than SEQ ID NO:3 and NO:4 (originally elected subject matter). Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41-49 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Objections/Rejections Withdrawn***

3. In light of amendment to the specification, the previous objection to the specification for lack of complete descriptions for the drawings is withdrawn.
4. In light of amendment to the claims, the previous objection to the specification for multiple dependent claims is withdrawn.

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5. In light of amendment to the claims, the previous rejection of claims 1-6 and 13-15 under 35 U.S.C. 101 for being drawn to non-statutory subject matter is withdrawn.

6. In light of cancellation of the claim, the previous rejection of claims 1-5 and 13-15 under 35 U.S.C. 112, second paragraph, for being indefinite with regard to an unspecified sequence is withdrawn.

7. In light of cancellation of claims 1 and 15, the previous rejection of said claims under 35 U.S.C. 112, second paragraph, for being indefinite with regard to “a derivative, homologue, analogue or mimetic thereof” and for “complementary” is withdrawn.

8. In light of cancellation of claims 1 and 13-15, the previous rejection of said claims under 35 U.S.C. 112, second paragraph, for lack of information concerning wash conditions and hybridization and wash buffers is withdrawn.

9. In light of cancellation of claims 2, 3, 5 and 15, the previous rejection of said claims under 35 U.S.C. 112, second paragraph, for “protein:molecule interacting region”, “protein:DNA binding region” and “protein:protein binding region” is withdrawn.

10. In light of cancellation of claims 13 and 14, the previous rejection of said claims under 35 U.S.C. 112, second paragraph, for “substantially set forth in” is withdrawn.

11. In light of cancellation of claims 13 and 14, the previous rejection of said claims under 35 U.S.C. 112, second paragraph, for “having” is withdrawn.

12. In light of cancellation of claims 13 and 14, the previous rejection of said claims under 35 U.S.C. 112, second paragraph, for “having at least 15% similarity to all or part of the listed sequences” is withdrawn.

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13. In light of cancellation of claims 1-5 and 13-14, the previous rejection of said claims under 35 U.S.C. 112, first paragraph, for lack of adequate written description is withdrawn.
14. In light of cancellation of claims 1-5, the previous rejection of said claims under 35 U.S.C. 112, first paragraph, for scope of enablement is withdrawn.
15. In light of cancellation of claims 13 and 14, the previous rejection of said claims under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn.
16. In light of cancellation of claims 1-5 and 15, the previous rejection of said claims under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn.
17. In light of cancellation of claims 13 and 14, the previous rejection of said claims under 35, U.S.C. 102(b) as being anticipated by Watson et al. is withdrawn.
18. In light of cancellation of claim 13, the previous rejection of said claims under 35 U.S.C. 102(e) as being anticipated by Smith et al. is withdrawn.
19. In light of cancellation of claim 14, the previous rejection of said claims under 35 U.S.C. 102(b) as being anticipated by Schaffer et al. is withdrawn.

***Claim Rejections - 35 USC § 101***

20. Claims 6-12 and 50-51 are rejected under 35 U.S.C. 101 because
21. Claims 6-12 and 50-51 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claimed invention is drawn to polynucleotides encoding SOCS box proteins wherein the binding partners and effector molecules of the SOCS box proteins are unknown. As such, the

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claimed invention does not have a specific and substantial asserted utility or a well-established utility. The issue of credibility will not be addressed in this office action.

Claims 6-12 and 50-51 are also rejected under 35 U.S.C. 112, **first paragraph**.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112***

22. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

23. Claims 6-12 and 50-51 are rejected under 35 U.S.C. 112, **first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are unpredictability in the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

The art teaches that “*The SOCS proteins share structural similarities. Each has an N-terminal region of variable length and highly variable amino acid sequence, a central SH2*

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*domain, and a striking region of C-terminal homology that we designated the SOCS box (4).*

*Given the sequence similarity evident in the SOCS box of the four SOCS proteins and its*

*conserved position at the C terminus of each protein, it seems likely that this domain has a*

*conserved and important function. To date, however, the role of each part of the protein in*

*inhibiting signal transduction is far from clear, although regions in addition to the SH2*

***domain appear to be required*** [emphasis added] (5)." (Proc. Natl. Acad. Sci. USA 95:114-119,

Jan., 1998, see especially page 114, right column, first paragraph) (reference previously

provided). In essence, the art, which comes from Inventors Hilton, Richardson, Alexander,

Viney, Willson, Starr, Nicholson, Metcalf and Nicola, teaches that a structure to function

relationship critical for SOCS proteins to modulate signal transduction was not known in 1998

(i.e. unpredictable), which is after Applicants' filing of the instant application. The skilled artisan

would recognize that the complete structure of the encoding sequence would be necessary to

make the claimed invention and information concerning the use of the claimed, complete structure

would be necessary to practice the claimed invention (see rejection above). Thus, anything short

of a completely defined structure would result in undue experimentation in order to define an

encoded, functional SOCS box protein. Since it is not routine in the art to engage in *de novo*

experimentation to make polynucleotides that encode SOCS proteins where the expectation of

success is unpredictable, the skilled artisan would require additional guidance in order to make

and use such polynucleotides. Without such guidance, the experimentation left to those skilled in

the art is undue.

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*Conclusion*

24. Claims 6-12 and 50-51 are rejected.
25. Claims 41-49 are withdrawn from further consideration.
26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devesh Srivastava, Ph.D. whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday-Thursday from 8:00 am to 5:30 pm and alternate Fridays from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph.D., can be reached on (703) 308-2923. The FAX phone number for the Art Unit where this application or proceeding is assigned is (703) 308-0294. For direct submission of official papers, by facsimile, with the Patent Office, the FAX phone number is (703) 308-4242 or (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Devesh Srivastava, Ph.D.  
Patent Examiner  
January 8, 2001

*Christopher S.-J. Low*  
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